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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,577	07/13/2001	Jeffrey C. Bottaro	8500-0262	4233

23980 7590 09/24/2003

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EXAMINER

DAVIS, BRIAN J

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicant No. .	Applicant(s)
	09/905,577	BOTTARO ET AL.
	Examiner	Art Unit
	Brian J. Davis	1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-62 and 78-80 is/are allowed.
- 6) Claim(s) 64-66,70-77 and 81 is/are rejected.
- 7) Claim(s) 63 and 67-69 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,6</u> .	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

***Election/Restriction Requirement Withdrawn***

**The examiner notes for the record that the oral election/restriction requirement of examiner Laurie Mayes made on 7/15/03 is hereby withdrawn. The application has been examined in its entirety. Applicant's election of the claims of group I and protriptylene as the elected Group and species, respectively, is acknowledged, but moot.**

Merely for completeness of the record, examiner Mayes' restriction grouping is reproduced below:

- I. Claims 1-57, drawn to a method for increasing the solubility of an ionizable compound in a lipophilic medium comprising admixing the ionizable compound with a N,N-dinitramide salt.
- II. Claims 58-80, drawn to a salt of N,N-dinitramide and a pharmaceutical preparation comprising a salt of N,N-dinitramide.
- III. Claim 81, drawn to a method of transmitting a pharmacologically active agent across the blood-brain barrier comprising administering a N,N-dinitramide salt.

***Claim Objections***

Claim 63 is objected to because of the following informalities: the examiner respectfully suggests that claim 63 should properly depend from claim 62. Its

dependency from claim 73 appears to be a typographical error. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64, 65, 70, 72, 73 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term 'effective amount' is indefinite where the claim fails to state the function which is to be rendered effective. *In re Frederiksen*, 102 USPQ 35 (CCPA 1954).

Claims 66, 71 and 74-77 are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite. *Ex parte Cordova*, 10 USPQ 2d 1949, 1952 (PTO Bd. App. 1989).

### ***Allowable Subject Matter***

Claims 1-62 and 78-80 allowed. Claims 67-69 are objected to as being dependent upon a claim that has been objected to. Claims 63-66, 70-77 and 81 would be allowable once the above objection and 112 rejections have been overcome. The following is a statement of reasons for the indication of allowable subject matter:

The closest prior art appears to be *Toxicology and Industrial Health*, 1998, 14(6), p. 789-798, cited by the applicants in the IDS, which teaches the administration of ADN

to rats in order to assess its toxicology. The reference neither teaches nor suggests, however, the instant method of increasing solubility of biologically active cationic species, nor the instant complexes or compositions. Nor would it have been obvious to one of ordinary skill in the art at the time of the invention to modify the cited prior art in order to arrive at that of the instant invention. There is no motivation to do so.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 3,726,901 is cited to show related oil-soluble derivatives of nitroamines.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 703-305-7129. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

  
**BRIAN DAVIS**  
PRIMARY EXAMINER

Brian J. Davis  
September 14, 2003